510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
ASSAY AND INSTRUMENT COMBINATION TEMPLATE

A. 510(k) Number:

k121433

B. Purpose for Submission:

New device

C. Measurand:

Capillary, venous and arterial whole blood glucose

D. Type of Test:

Quantitative, Amperometric method, Glucose Dehydrogenase (GDH-FAD)

E. Applicant:

HMD Biomedical

F. Proprietary and Established Names:

GoodLife CS-200 Blood Glucose Monitoring System (single patient use)

GoodLife CS-200 Professional Blood Glucose Monitoring System (multiple patient use)

G. Regulatory Information:

Regulation Section	Classification	Product Code	Panel
21 CFR § 862.1345	Class II	LFR, Glucose dehydrogenase, glucose	Clinical Chemistry (75)
21 CFR § 862.1345	Class II	NBW, system, test, blood glucose, over the counter	Clinical Chemistry (75)

H. Intended Use:

1. Intended use(s):

See indications for use below.

2. Indication(s) for use:

The GoodLife CS-200 Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only. The GoodLife CS-200 Blood Glucose Monitoring System is intended to be used by a single person and should not be shared.

The GoodLife CS-200 Blood Glucose Monitoring System is intended for self testing outside the body (in vitro diagnostic use) by people with diabetes at home as an aid to monitor the effectiveness of diabetes control. The GoodLife CS-200 Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GoodLife KP Blood Glucose Test Strips are for use with the GoodLife CS-200 Blood Glucose Meter to quantitatively measure glucose (sugar) in fresh capillary whole blood samples drawn from the fingertips only.

The GoodLife CS-200 Professional Blood Glucose Monitoring System is intended to be used for the quantitative measurement of glucose (sugar) in venous or arterial whole blood or fresh capillary drawn from the fingertips. It is intended for testing outside the body (in vitro diagnostic use) and is intended for multiple-patient use in professional healthcare settings as an aid to monitor the effectiveness of a diabetes control program. This system should only be used with single-use, auto-disabling lancing devices.

The GoodLife CS-200 Professional Blood Glucose Monitoring System should not be used for the diagnosis of or screening of diabetes or for neonatal use.

The GoodLife KP Professional Blood Glucose Test Strip is for use with the GoodLife CS-200 Professional Blood Glucose Meter to quantitatively measure glucose (sugar) in venous or arterial whole blood or fresh capillary drawn from the fingertips.

3. Special conditions for use statement(s):

Not for neonatal use, nor for screening for or diagnosis of diabetes mellitus.

Not for use on critically ill patients, patients in shock, dehydrated patients, hypotensive patients or hyperosmolar patients.

Single-patient use devices are for single patients only and should not be shared.

Multiple-patient use meters must be disinfected between use following labeling recommendations

Multiple patient use systems should only use single use, auto disabling lancing devices.

4. Special instrument requirements:

   GoodLife CS-200 Blood Glucose Meter

   GoodLife CS-200 Professional Blood Glucose Meter

I. Device Description:

GoodLife CS-200 Blood Glucose Monitoring System and GoodLife CS-200 Professional Blood Glucose Monitoring System consist of:

- Glucose Meter
- Glucose Test Strips
- Two levels of glucose control solutions (Level I and Level II). Glucose Control solutions were previously cleared under K032985.
- Check Strip
- Instructions for use

J. Substantial Equivalence Information:

1. Predicate device name(s):

   TaiDoc Technology Corporation U-RIGHT TD-4279A Blood Glucose Monitoring System

2. Predicate 510(k) number(s):

   k101509

3. Comparison with predicate:

Similarities – CS 200		
Item	Candidate Device	Predicate device TaiDoc U-RIGHT TD-4279A Blood Glucose Monitoring System (k101509)
Indications for Use	Quantitative measurement of glucose in capillary whole blood	Quantitative measurement of glucose in capillary and venous whole blood
Operating principle / methodology	Same	Amperometric
Test time	Same	5 seconds
Enzyme	Same	Glucose dehydrogenase
Measuring range	Same	20 – 600 mg/dL
Operating temperature range	Same	10 – 40° C
Units	Same	mg/dL

Differences – CS 200		
Item	Candidate Device	Predicate device TaiDoc U-RIGHT TD-4279A Blood Glucose Monitoring System (k101509)
Hematocrit range	30 – 55%	20 – 70%
Calibration	Coding required	No code
Sample volume	0.5 µL	1.1 µL
Size L x W x H (mm)	90 x 56 x 19	94.9 x 52 x 15
Weight	70 g	67.6 g
Maximum altitude	8,800 feet	10, 742 feet
Operating humidity range	20 – 80% RH	< 85% RH

Similarities – CS 200 Professional		
Item	Candidate Device	Predicate device TaiDoc U-RIGHT TD-4279A Blood Glucose Monitoring System (k101509)
Indications for Use	Quantitative measurement of glucose in capillary, venous, and arterial whole blood	Quantitative measurement of glucose in capillary and venous whole blood
Operating principle / methodology	Same	Amperometric
Test time	Same	5 seconds
Enzyme	Same	Glucose dehydrogenase
Measuring range	Same	20 – 600 mg/dL
Operating temperature range	Same	10 – 40° C
Units	Same	mg/dL

Differences – CS 200 Professional		
Item	Candidate Device	Predicate device TaiDoc U-RIGHT TD-4279A Blood Glucose Monitoring System (k101509)
Hematocrit range	30 – 55%	20 – 70%
Calibration	Coding required	No code
Sample volume	0.5 µL	1.1 µL
Size L x W x H (mm)	90 x 56 x 19	94.9 x 52 x 15
Weight	70 g	67.6 g

Differences – CS 200 Professional		
Item	Candidate Device	Predicate device TaiDoc U-RIGHT TD-4279A Blood Glucose Monitoring System (k101509)
Maximum altitude	8,800 feet	10, 742 feet
Operating humidity range	20 – 80% RH	< 85% RH

K. Standard/Guidance Document Referenced (if applicable):

CEN 13640 Stability Testing of in Vitro Diagnostic Reagents

CLSI EP05-A2 Evaluation of Precision Performance of Quantitative Measurement Methods; Approved Guideline-Second Edition

CLSI EP06-A: Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach.

CLSI EP07-A: Interference Testing in Clinical Chemistry; Approved Guideline-Second Edition.

ISO 14971 Medical devices - Application of risk management to medical devices

ISO 15197:2003 In Vitro Diagnostic Test Systems - Requirements for blood-glucose monitoring systems for self-testing in managing diabetes mellitus

L. Principle:

When the blood is drawn into the blood reaction zone of the test strip, the glucose in the blood sample mixes with a special chemical in the test strip, which produces a small electric current. The reaction current is proportional to the amount of glucose in the blood. The result is displayed on the LCD monitor and automatically stored in the meter for future use.

M. Performance Characteristics (if/when applicable):

1. Analytical performance:

a. Precision/Reproducibility:

Repeatability was evaluated by analyzing venous whole blood samples spiked to six different glucose concentrations. The hematocrit of all samples was between 30 and 55%. Three lot numbers of test strips and ten meters were used in the study and each of the six samples was measured ten times per strip lot per meter for a total of 100 measurements per glucose concentration. Results are summarized below:

Test Strip Lot 1

Glucose conc. (mg/dL)	30-50	51-110	111-150	151-250	251-400	401-600
n	100	100	100	100	100	100
Mean (mg/dL)	42.3	104.1	122.0	198.6	334.2	569.2
Std Dev (mg/dL)	1.7	4.2	3.5	6.3	12.6	21.2
CV (%)	4.0	4.0	2.9	3.2	3.8	3.7

Test Strip Lot 2

Glucose conc. (mg/dL)	30-50	51-110	111-150	151-250	251-400	401-600
n	100	100	100	100	100	100
Mean (mg/dL)	43.0	102.7	123.9	206.8	343.6	570.2
Std Dev (mg/dL)	1.6	3.5	4.9	9.1	14.0	24.7
CV (%)	3.9	3.4	4.0	4.4	4.1	4.3

Test Strip Lot 3

Glucose conc. (mg/dL)	30-50	51-110	111-150	151-250	251-400	401-600
n	100	100	100	100	100	100
Mean (mg/dL)	43.2	104.0	121.4	192.0	304.3	554.5
Std Dev (mg/dL)	1.7	3.5	4.1	6.6	11.0	21.7
CV (%)	4.0	3.4	3.3	3.4	3.6	3.9

Intermediate Precision was evaluated by analyzing control samples at three different concentrations. Three lots of test strips and ten meters were used in the study. Each of the control levels was measured once per day over twenty days for each of the ten meters. In total, 200 measurements were taken for each of the three levels. Results are summarized below:

Lot 1

Control solution assigned value (mg/dL)	Level 1	Level 2	Level 3
n	100	100	100
Mean (mg/dL)	44.3	110.2	353.5
Std Dev (mg/dL)	2.0	3.9	13.4
CV (%)	4.4	3.6	3.8

Lot 2

Control solution assigned value (mg/dL)	Level 1	Level 2	Level 3
n	100	100	100
Mean (mg/dL)	44.4	109.5	350.0
Std Dev (mg/dL)	1.9	4.3	12.5
CV (%)	4.4	3.9	3.6

Lot 3

Control solution assigned value (mg/dL)	Level 1	Level 2	Level 3
n	100	100	100
Mean (mg/dL)	44.4	110.4	355.4
Std Dev (mg/dL)	2.1	4.4	16.5
CV (%)	4.7	4.0	4.6

b. Linearity/assay reportable range:

The sponsor evaluated the linearity of the meter by preparing a series of eight glucose samples, following the dilution scheme in CLSI EP6-A, and producing target values of 13, 42, 103, 119, 231, 337, 449, and 659 mg/dL.

Each of the eight levels was analyzed twenty times using two lots of test strips. All samples were also tested on the YSI 2300 analyzer. Linear regression of the data produced the following:

Strip lot	Line equation	95% CI slope	95% CI intercept	r^2	n
1	y = 0.99x +4.87	± 0.01	± 2.12	0.999	160
2	y = 0.97x +4.94	± 0.01	± 2.92	0.998	160
3	y = 0.95x +7.06	± 0.01	± 2.82	0.998	160
combined	y = 0.97x +5.62	± 0.01	± 1.64	0.998	480

The results of the study support the sponsor's claimed glucose measurement range of 20 – 600 mg/dL.

c. Traceability, Stability, Expected values (controls, calibrators, or methods):

Traceability:

The CS-200 Glucose Monitoring System is traceable to the YSI 2300 Glucose analyzer. The YSI 2300 is calibrated using the YSI 2747 Glucose Standard which is NIST traceable.

Test Strip Stability

Closed vial (shelf life)

Test strip shelf life stability was assessed in real time studies. Testing protocols and acceptance criteria for the GoodLife KP Blood Glucose Test Strip were reviewed and found to be acceptable. The testing supported the claimed shelf life stability of 24 months at the recommended storage temperatures of 50 – 104° F.

Opened vial (in-use)

Test strip opened vial stability was assessed in real time studies. Testing protocols and acceptance criteria for the GoodLife KP Blood Glucose Test Strip were reviewed and found to be acceptable. The testing supported the claimed opened vial stability of 90 days at the recommended storage temperatures of 50 – 104° F.

Control Solution Value Assignment and Stability:

Value assignment for the GoodLife Glucose Control Solutions using the GoodLife CS-200 Blood Glucose Monitoring System was calculated with replicate measurements of each control on five meters. Testing protocols and acceptance criteria were reviewed and found to be acceptable

Control stability claims of an 18 month shelf life and 90 days open-vial when stored at 50 – 86° F were validated in k032985.

d. Detection limit:

The measuring range of the device is 20 - 600 mg/dL. This range was validated by the linearity study (M.1.b).

e. Analytical specificity:

The sponsor performed interference studies in accordance with CLSI EP7-A. Testing was performed in parallel (control samples vs. test samples) to minimize the effects of glucose metabolism. The glucose levels tested were approximately 65 and 310 mg/dL by the reference method, and were produced by spiking into venous blood samples. Four concentrations of each potential interferent were tested at each glucose level. The sponsor defined no significant interference as ≤ 10%. The following substances did not cause significant interference at the concentrations listed:

Substance	**No interference up to (mg/dL unless otherwise noted):**
Acetaminophen	20
Ascorbic Acid	2.25
Bilirubin	40
Cholesterol	500
Creatinine	10
Dopamine	20
Ephedrine	10
Ethanol	400
Fructose	40
Galactose	100
Gentisic Acid	2
Glutathione	60
Hemoglobin	450
Ibuprofen	50
Lactose	20
L-Dopa	0.8
Maltose	200
Methyl-dopa	1.6
Salicylate	50
Sorbitol	10
Tetracycline	1.6
Tolazamide	6.25
Tolbutamide	64
Triglyceride	1000
Urea	600
Uric Acid	15
Xylose	50

The sponsor has the following limitations in their labeling:

High concentrations of triglycerides (>1,000mg/dL), ascorbic acid (>2.25 mg/dL), xylose (> 50 mg/dL) and uric acid (>15 mg/dL) may affect the test results.

f. Assay cut-off:

Not Applicable.

2. Comparison studies:

a. Method comparison with predicate device:

System Accuracy Study (capillary blood)

For this study, 90 capillary blood samples from the finger with concentrations from 50 – 391 mg/dL were collected and analyzed by a healthcare professional on the GoodLife CS-200 Professional Blood Glucose Meter. Five additional samples at concentrations < 50 mg/dL and five additional samples at concentrations > 400 mg/dL were also analyzed. Low concentrations were achieved by allowing samples to glycolyze and high concentration samples were achieved by spiking. Three lots of test strips were used to collect the data and all results were compared to the YSI glucose reference method. Results are summarized below:

n = 100
y = 1.014x + 0.7458
r^2 = 0.9729
Sy.x= 17.82
Concentration Range: 41-489 mg/dL

Glucose concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
8/18 (44%)	16/18 (89%)	18/18 (100%)

Glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
37/82 (45%)	67/82 (82%)	75/82 (91%)	80/82 (98%)

b. Matrix comparison:

System Accuracy Study (venous blood)

For this study, 90 venous blood samples with concentrations from 53 – 399 mg/dL were collected and analyzed by a healthcare professional on the the GoodLife CS-200 Professional Blood Glucose Meter. Five additional samples at concentrations < 50 mg/dL and five additional samples at concentrations > 400 mg/dL were also analyzed. Low concentrations were achieved by allowing samples to glycolyze and high concentration samples were achieved by spiking. Three lots of test strips were used to collect the data and all results were compared to the YSI glucose reference method. Results are summarized below:

n = 100
y = 1.0083x + 2.3596
r^2 = 0.9731
Sy.x= 19.11
Range: 31 – 489 mg/dL

Glucose concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
6/14 (43%)	13/14 (93%)	14/14 (100%)

Glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
34/86 (40%)	66/86 (77%)	77/86 (90%)	84/86 (98%)

System Accuracy Study (arterial blood)

For this study, 90 arterial blood samples with concentrations from 53 – 396 mg/dL were collected and analyzed by a healthcare professional on the GoodLife CS-200 Professional Blood Glucose Meter. Five additional samples at concentrations < 50 mg/dL and five additional samples at concentrations > 400 mg/dL were also analyzed. Low concentrations were achieved by allowing samples to glycolyze and high concentration samples were achieved by spiking. Three lots of test strips were used to collect the data and all results were compared to the YSI glucose reference method. Results are summarized below:

n = 100
y = 0.9879 + 2.3162
r^2 = 0.968
Sy.x = 20.78
Range: 31 – 489 mg/dL

Glucose concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
6/14 (43%)	13/14 (93%)	14/14 (100%)

Glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
33/86 (38%)	61/86 (71%)	76/86 (88%)	84/86 (98%)

3. Clinical studies:

a. Clinical Sensitivity:

Not Applicable.

b. Clinical specificity:

Not Applicable.

c. Other clinical supportive data (when a. and b. are not applicable):

Lay User Study (capillary blood only)

For this study, 150 naive lay users collected and analyzed their own fingerstick capillary blood samples using the GoodLife CS-200 Blood Glucose Meter. The participants did not receive any training other than to read the English labeling provided with the GoodLife CS-200 Blood Glucose Monitoring System. Within 5 minutes a second capillary fingerstick sample was collected for analysis on the YSI reference method. Three lots of test strips were used to collect the data. Results are summarized below:

n = 150
y = 1.001x + 1.4112
r^2 = 0.9601
Sy.x= 19.76
Range: 41-395 mg/dL

Glucose concentration < 75 mg/dL

Within ± 5 mg/dL	Within ± 10 mg/dL	Within ± 15 mg/dL
16/18 (89%)	18/18 (100%)	18/18 (100%)

Glucose concentration ≥ 75 mg/dL

Within ± 5%	Within ± 10%	Within ± 15%	Within ± 20%
57/132 (43%)	108/132 (82%)	125/132 (95%)	129/132 (98%)

4. Clinical cut-off**:**

   Not Applicable.

5. Expected values/Reference range:

   Expected blood glucose values for nondiabetic adults are as follows:

   Before meals < 100 mg/dL
   After meals < 140 mg/dL

   Reference:

   Source: American Diabetes Association Position Statement, Diabetes Care Vol.35 (Suppl.1) p.S13 (2012)

N. Instrument Name:

GoodLife CS-200 Blood Glucose Meter (single patient use)

GoodLife CS-200 Professional Blood Glucose Meter (multiple patient use)

O. System Descriptions:

1. Modes of Operation:

   Each test strip is single use and must be replaced with a new strip for additional measurements. The minimum sample size is 0.5 µL.

   Does the applicant's device contain the ability to transmit data to a computer, webserver, or mobile device?

   ☐ Yes ☐ No

   Does the applicant's device transmit data to a computer, webserver, or mobile device using wireless transmission?

   ☐ Yes ☐ No

2. Software:

   FDA has reviewed applicant's Hazard Analysis and software development processes for this line of product types:

   ☐ Yes ☐ No

   The applicant has provided documentation that indicates the device was designed and developed under good software life-cycle processes.

3. Specimen Identification:

   There is no sample identification function with this device. Samples are applied directly to the test strip as they are collected.

4. Specimen Sampling and Handling:

   The device is intended to be used with capillary, venous, or arterial whole blood. The whole blood sample is applied directly to the test strip by capillary action.

5. Calibration:

   The meter must be coded (calibrated) through the use of a code strip that is included with every vial of test strips.

6. Quality Control:

   Glucose control solutions at two different concentrations can be analyzed with this device, and

are included in the starter kit. Recommendations on when to test the control materials are provided in the labeling. An acceptable range for each control level is printed on the glucose strip vial label. The user is cautioned not to use the meter if the control result falls outside these ranges.

P. Other Supportive Instrument Performance Characteristics Data Not Covered In The "Performance Characteristics" Section above:

1. Hematocrit Study

   In this study, one strip lot was tested on one meter in replicates of six at each of the following hematocrit levels: 25, 30, 35, 40, 45, 55, and 60%. The glucose levels in venous blood samples fell into six categories: 20 – 50, 51 – 110, 111 – 150, 151 – 250, 251 – 400, and 401 – 600 mg/dL. A single replicate was obtained for each combination of test strip/glucose level/hematocrit and donor. This resulted in n = 252 data points (6 glucose levels x 7 hematocrit levels x 6 replicates per sample). Glucose concentrations were verified by the YSI reference method. The bias relative to the reference method was acceptable to support the claim that hematocrit levels of 30 to 55% do not significantly affect the glucose results.

2. Sample Volume Study

   The sponsor performed a sample volume study to support the claimed minimum sample volume requirement for the GoodLife CS-200 Blood Glucose Monitoring System (0.5 µL) using blood samples at six glucose concentrations (44, 80, 131, 207, 314, and 508 mg/dL). Results support the claimed sample volume of 0.5 µL.

3. Altitude Study

   In this study, one test strip lot was tested on four meters on blood samples adjusted into six categories: 20 – 50, 51 – 110, 111 – 150, 151 – 250, 251 – 400, and 401 – 600 mg/dL. The samples were tested at three altitude levels: sea level, 5,741 feet, and at 8,800 feet. Each combination of altitude / sample / meter was tested in replicates of 5. This resulted in n = 360 data points (3 altitudes x 6 glucose levels x 4 meters x 5 replicates). Glucose concentrations were verified by the YSI reference method. The bias relative to the reference method was acceptable to support the claim that altitudes up to 8,800 feet do not significantly affect the glucose results.

4. Temperature and Humidity Studies

   In this study, one test strip lot was tested on two meters at eight glucose concentrations at ten combinations of temperature and humidity. Each combination of environmental conditions / glucose concentration / meter was tested in replicates of 5. This resulted in n = 800 data points (10 environmental conditions x 8 glucose concentrations x two meters x 5 replicates). The temperatures tested were 46, 50, 77, 104, and 108° F. The relative humidities tested were 15 and 85%. Glucose concentrations were verified by the YSI

reference method. The bias relative to the reference method was acceptable to support the claim that temperatures from 10 – 40° C (50 – 104° F) and relative humidities from 20 – 80% do not significantly affect the glucose results.

5. Infection Control Studies

   The GoodLife CS-200 Blood Glucose Monitoring System is intended for single-patient use. The GoodLife CS-200 Professional Blood Glucose Monitoring System is intended for multiple-patient use. Disinfection efficacy studies were performed on the materials comprising the meter by an outside commercial testing facility demonstrating complete inactivation of hepatitis B virus (HBV) with the chosen disinfectant, Clorox Germicidal Wipes (EPA Registration Number 67619-12). Robustness studies were also performed by the sponsor demonstrating that there was no change in performance or external materials for the meter after 13,688 cleaning and disinfection cycles with Clorox Germicidal Wipes. The robustness studies were designed to simulate 5 years of multiple-patient use. Labeling was reviewed for adequate instructions for the validated cleaning and disinfection procedures.

6. EMC testing

   Electromagnetic Compatibility and Electrical Safety testing were performed in accordance with EN 60601-1, EN 60601-1-2, EN 61010-1, EN 61010-2-101and EN 61326-1. The device satisfied all of the requirements.

7. Readability Assessment

   The sponsor provided a readability assessment on the User Guide, Test Strip Insert, and Control Solution Insert. The Flesch-Kincaid analysis produced a grade level of 7.8, 7.9, and 7.9 respectively.

8. Toll free Customer service is available Mon–Fri 9:00 am - 4:30 pm (Pacific Time) by calling 1-855-692-3511. Uses are instructed to call their healthcare professional at all other times.

Q. Proposed Labeling:

The labeling is sufficient and it satisfies the requirements of 21 CFR Part 809.10.

R. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.